Diabetes and Vaccines

Q & A

At a glance: In 1998 a researcher presented a theory suggesting that vaccines, depending on when they are administered, may increase or decrease the risk that certain people may develop type 1 diabetes, previously called juvenile onset or insulin-dependent diabetes mellitus (IDDM). The cause of type 1 diabetes is not completely understood but it is believed that genetic and environmental factors may be involved. Vaccinations have been studied as a possible environmental risk factor and the scientific studies conducted have found no relationship between immunizations and type 1 diabetes.

What is diabetes?

- Most of the food we eat is turned into glucose, or sugar, for our bodies to use for energy. The pancreas, an organ that lies near the stomach, makes a hormone called insulin to help glucose get into the cells of our bodies. If a person has diabetes, their body can't make enough insulin or can't use its own insulin as well as it should. This causes sugar to build up in the blood. Diabetes is classified into two main types:
- Type 1 – Previously known as insulin-dependent diabetes mellitus (IDDM) or juvenile diabetes. In Type 1 diabetes, which accounts for 5-10% of all diabetes cases, the body does not produce insulin. Risk factors are less well defined for type 1 diabetes than for type 2 diabetes, but genetic, environmental and autoimmune factors are involved in the development of this type of diabetes.
- Type 2 – Previously known as non-insulin dependent diabetes mellitus (NIDDM) or adult-onset diabetes. In Type 2 diabetes, which accounts for 90-95% of all cases of diabetes, either the body does not produce enough insulin or the insulin does not work. Risk factors for type 2 diabetes include older age, obesity, family history, impaired glucose tolerance, physical inactivity and race/ethnicity (African Americans, Hispanic/Latino Americans, Native Americans, and some Asian Americans and Pacific Islanders are at increased risk).

In discussion below, "diabetes" refers to type 1.

For more information about diabetes, see the Centers for Disease Control and Prevention's diabetes program website at http://www.cdc.gov/diabetes/

Do vaccines cause diabetes?

No. Carefully performed scientific studies show that vaccines do not cause diabetes or increase a person's risk of developing diabetes (DeStefano 2001, EURODIAB Substudy 2 Study Group 2000, Karvonen 1999, Heijbel 1997, Parent 1997, Dahlquist 1995, Hyoty 1993, Blom 1991). In 2002, the Institute of Medicine reviewed the existing studies and released a report concluding that the scientific evidence favors rejection of the theory that immunizations cause diabetes. Furthermore, DeStefano and colleagues (2001) recently conducted the first study looking at whether the timing of childhood vaccinations,

particularly of Hepatitis B, is related to the risk of a child getting diabetes. This study, which examined data from 1,020 children in the U.S., did not show an association between any of the recommended childhood vaccines and diabetes, regardless of when the vaccines were given. Other studies also provide evidence that vaccination does not cause diabetes:

- A European study that examined 900 diabetic and 2,302 non-diabetic children found a slight relationship between infections during early infancy and risk of developing diabetes. However, the researchers did not find a relationship between any of the common childhood infections or childhood vaccines and diabetes in children. (EURODIAB Substudy 2 Study Group 2000)
- A study conducted in Sweden looked at 1,267 diabetic children in two groups: a group of children that were born during the time that pertussis vaccination was used and a group of children that were born after pertussis vaccine had been removed from the immunization schedule. The researchers found no difference in the incidence rate of diabetes between the children born before and the children born after 1979, when pertussis was excluded from routine immunizations in Sweden. (Heijbel 1997)
- The results from a study that examined 339 diabetic and 528 non-diabetic Swedish children showed that children that received measles vaccine were slightly protected against getting diabetes. The study showed no relationship, positive or negative, between tuberculosis, smallpox, tetanus, whooping cough, rubella and mumps vaccines and diabetes in children. (Blom 1991)

What about evidence that suggests that vaccines cause diabetes?

The only evidence suggesting a relationship between vaccination and diabetes comes from Dr. John B. Classen (Classen 1996; Classen and Classen 1997; Classen and Classen 2002). He has suggested that certain vaccines if given at birth may decrease the occurrence of diabetes, whereas if initial vaccination is performed after 2 months of age the occurrence of diabetes increases. Dr. Classen's studies have a number of limitations and have not been verified by other researchers.

- This theory is based on results from experiments in laboratory animals, as well as comparisons of the rates of diabetes between countries with different immunization schedules (Classen, 1996; Classen & Classen 1997). Applying findings from laboratory animals to humans is fraught with uncertainty. Findings that are noted in animals cannot be directly applied to people because of the large biological differences. In addition, many of the animal experiments involved anthrax vaccine, which is not used in infants and children.
- Comparison of diabetes rates between countries provides weak evidence because many factors, including vaccination schedules, may differ by country. For instance, comparisons between countries included vaccines that are infrequently used in the U.S. (BCG) or are no longer used (smallpox). Furthermore, factors such as genetic predisposition and a number of possible environmental exposures unrelated to vaccines, may influence the development of diabetes in different countries.

Dr. Classen also performed an analysis of data from a large study conducted in Finland of Haemophilus influenzae type B (Hib) vaccine. Over 100,000 children were randomly

assigned to receive either 4 doses of vaccine starting at 3 months of age or a single dose at 24 months. Over about a 10-year follow up period, 205 children in the multiple dose group developed diabetes compared with 185 in the single dose group.

- These results are inconclusive because the exact number of children in each group is not known and the noted differences may not be statistically significant (that is, they could be due to "chance").
- The results from a similar study using the same data from Finland were not the same as Dr. Classen's results (Karvonen et al. 1999). This study was similar to Dr. Classen's study except that it compared children in 3 (rather than 2) different groups: 1) children that were born before Hib vaccination was recommended (and therefore did not receive the shot as part of their routine immunizations), 2) children that began receiving Hib vaccine at 3 months of age, and 3) children that received a single dose of Hib at 24 months. This study did not find a difference in diabetes risk between any of the 3 groups of children.

Dr. Classen recently performed another analysis using the same data from the group of children in Finland (Classen and Classen 2002). In this study Dr. Classen suggests that by the age of 7 years old a greater number of diabetes cases occurred in Finnish children that had received the Hib vaccine than in children that had not received the vaccine.

- In order for an association between Hib vaccination and diabetes to be confirmed, the results would have to be replicated in several other scientific studies. No other studies, not even one using the exact same data from the children in Finland (Karvonen 1999), have found a relationship between Hib vaccine and an increase in diabetes (DeStefano 2001, EURODIAB Substudy 2 Study Group 2000).
- It appears that Dr. Classen may have conducted his statistical analysis after seeing the results and noting that the largest difference was apparent by 7 years. The validity of this type of 'post-hoc' statistical testing, however, is highly questionable. When the full 10 years of follow-up was evaluated the differences were not statistically significant, which is also what was found by Karvonen and colleagues.

What is being done to monitor the safety of vaccines?

To assure the safety of vaccines, The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and other Federal agencies routinely monitor vaccine safety and conduct research to examine any new evidence that would suggest possible problems with the safety of vaccines. The CDC's Vaccine Safety Datalink (VSD) project links the immunization and medical records on members of seven HMOs, totaling 2.5% of the US population for various vaccine safety studies. The VSD project is a powerful and cost-effective tool for the on-going evaluation of vaccine safety. The Vaccine Adverse Event Reporting System, or VAERS, was designed to give health care workers and others a place to report possible problems following vaccination. VAERS helps the FDA and CDC to continuously monitor vaccine safety. To request a VAERS form or to get more information about VAERS, please call 1-800-822-7967 or go to the VAERS website http://www.vaers.org. For more information about vaccines and vaccinations, contact CDC's National Immunization Information Hotline:

English: 1-800-232-2522
Spanish: 1-800-232-0233
Or, visit the CDC's National Immunization Program's web site: http://www.cdc.gov/nip

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